spectrum

RE: Elemental Impurities – L-Asparagine, Monohydrate, FCC, EP, bioCERTIFIED™ (Cat# A9602)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	Lot specific analysis*
Lead	Pb	1	Lot specific analysis*
Arsenic	As	1	Lot specific analysis*
Mercury	Hg	1	Lot specific analysis*
Cobalt	Co	2A	Lot specific analysis*
Vanadium	V	2A	Lot specific analysis*
Nickel	Ni	2A	Lot specific analysis*
Thallium	TI	2B	Not Tested**
Gold	Au	2B	Not Tested**
Palladium	Pd	2B	Not Tested**
Iridium	lr	2B	Not Tested**
Osmium	Os	2B	Not Tested**
Rhodium	Rh	2B	Not Tested**
Ruthenium	Ru	2B	Not Tested**
Selenium	Se	2B	Not Tested**
Silver	Ag	2B	Not Tested**
Platinum	Pt	2B	Not Tested**
Lithium	Li	3	Not Tested**
Antimony	Sb	3	Not Tested**
Barium	Ba	3	Not Tested**
Molybdenum	Мо	3 3	Not Tested**
Copper	Cu	3	Not Tested**
Tin	Sn	3	Not Tested**
Chromium	Cr	3	Not Tested**

*Refer to CofA for lot specific analysis.

**Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

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Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com.</u>

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

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AN ISO 9001:2015 REGISTERED COMPANY